

Dockets Management Branch (HFA-305) Food and Drug Administration Room 1061 5630 Fishers Lane Rockville, Maryland 20852

Re: Proposed Regulations for Prior Notice of Imported Food

FDA Docket No. 02N-0278

Dear Sir or Madam:.

I am writing on behalf of Jen-Coat, Inc. to provide comment on the proposed FDA regulations resulting from the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. Jen-Coat, Inc. is an Extrusion coating, laminating, metallizing and printing company that provides product to consumer flexible packaging, industrial, and medical customers. Many of our products are designed for, and employed in, direct food contact end uses and are manufactured to be compliant with long standing FDA regulations.

Jen-Coat, Inc., as a member company of the American Forest and Paper Association (AF&PA) supports the AF&PA position on the proposed FDA regulations.

- 1. FDA's proposed inclusion of food packaging and other food contact substances in the definition of "Article of Food" is not consistent with Congressional intent.
- 2. Inclusion of food packaging and other food contact materials is not consistent with FDA's Food Security Preventive Measures Guidance.
- 3. Subjecting food packaging and food contact substances and articles to prior notice will not further the purposes of the Bioterrorism Act.
- 4. Separate notification for food packaging and food contact articles is duplicative.
- 5. FDA underestimates the burden of the proposed regulation.

I believe the proposal as written is too broad and will impose unnecessary burden on food packaging companies. It appears the regulation creates a duplication of effort from existing FDA regulations. The prior notification effort should focus on articles of food and not include food packaging and other food contact articles not in contact with food at the time of import. This was Congress's intent and also reflects an accurate assessment of the risk for terrorism induced contamination of imported packaging components. Jen-Coat, Inc. purchases a large volume of paper from Canada and we are concerned about the potential for bottlenecks at the border delaying critical shipments. In my opinion, FDA's goal to protect the safety of the United States food supply will be better served focusing on significant threats to contamination of articles of food and not on imported packaging components that do not come in contact with food.

I appreciate the opportunity to provide feedback on the proposed regulation and request the FDA consider the effect this broad interpretation of "food" will have on our industry.

Sincerely,

William Keefe

Quality Assurance Manager

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